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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,969	06/25/2003	Guohua Chen	ARC 3135 R1	6463

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

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10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/606,969	CHEN ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,7-26,29-34,36,38,39,44-56,59,60 and 105-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,7-26,29-34,36,38,39,44-56,59,60 and 105-124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' remarks and amendments, filed 9-21-2007, have been received. Claims 2, 7 – 26, 29 – 34, 36, 38, 39, 44 – 56, 59, 6, and 105 – 124 are pending and are considered on the merits below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7 – 26, 29 – 34, 36, 38, 39, 44 – 56, 59, 6, and 105 – 124 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Note that some of the grounds for this rejection which were discussed in the previous office action have been overcome. All of the issues still remaining that relate to this rejection are discussed below.

Claims 2, 29, and 105 recite "substantially all". It is not clear how much material may remain after "substantially all" is released. 1%? 2%? 30%? Some other amount? The artisan is not appraised of the meaning of this term, and thus is unable to determine the metes and bounds of the claim.

Claims 15, 17, 29 – 33, 36, 38-39, 49, 113 – 115 recite "lactic acid-based polymer". The meaning of this term is unclear. Applicants' remarks point to paragraph [0080] in an attempt to show that this term is defined. However, paragraph [0080] merely states examples of what a "lactic acid-based polymer" *can* be; the paragraph

never states what a "lactic acid-based polymer" *actually is* in such a way as to show the metes and bounds of this term. The so-called 'definition' in paragraph [0080] is not a definition at all, but merely an example, which does not serve to define this indefinite term.

The remaining claims are rejected for depending on at least one abovementioned claim, thereby incorporating the indefinite limitations thereof.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 7 – 23, 29 – 34, 36, 38, 39, 44, 45, 47 – 56, 59, 60, 105 – 121 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/238185 for reasons of record and those discussed below.

Claims 24 – 26, 46, 55, and 56 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/238185 in view of WO 0/74650 for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants argue that the '185 reference does not teach a composition where "substantially all" of the drug is delivered in a duration of less than about seven days. The term "substantially all" is indefinite as discussed above, and may be interpreted in

several ways. In one interpretation, the 74% and 75% of drug released within three days (in Example 6 of the '185 reference) reads on "substantially all" of the drug. However, even if "substantially all" was understood to mean "more than 99%", the composition of the '185 reference would meet this limitation. The composition in '185 delivers 53% or 62% of the drug in one day, and 75% or 74% of the drug in three days, after which time it is removed. Extrapolating to seven days, if the composition of '185 were not removed, it clearly would deliver more than 99% of the drug. This would require the removal of only about an average of 4.5% of the (originally present) amount of drug per day over the final four days. Since the device delivers more than half of the drug within one day, and an average of an additional 6% - 11% of (originally present) drug per day on the subsequent two days, it is reasonable to conclude that the device is indeed "selected to deliver substantially all of the beneficial agent" in seven days or less, and that in the example it is prevented from doing this only because it is removed prematurely (that is, before all the beneficial agent has been delivered).

New claims 122 – 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/238185 in view of US 6,130,200 to Brodbeck.

The teachings of the WO reference have been discussed previously.

What is lacking is a teaching of releasing no greater than specified amounts on the first day.

The Brodbeck reference teaches that it is advantageous to reduce the initial burst of injectable gel dosage forms (col. 18). Brodbeck teaches that this can be

accomplished by varying the viscosity of the gel. Brodbeck recognizes that this may make the gel difficult to inject, but this problem can be solved by adding emulsifiers or by heating the gel prior to injection (col. 18).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to lower the initial burst (that is, the amount of drug released in day 1) in the dosage form of '185. The motivation comes from Brodbeck, who teaches that such initial burst is disadvantageous. Since Brodbeck teaches how to solve the problem, and also teaches how to overcome problems associated with the solution, the artisan would enjoy a reasonable expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615

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